

### REMARKS

Reconsideration of the present application in view of the above amendment and following remarks is respectfully requested. As set forth above, Applicants hereby submit that claim 29 has been amended to more clearly define the subject matter encompassed by the Applicants' invention. No new matter has been added. Therefore, claims 29, 31-32, 35-37, 40-42, 44, 45, 47-51, and 53-67 are currently pending.

### **REJECTION UNDER U.S.C. § 102(e)**

In the Office Action, claims 29, 32, 40, 45, 47-51, 53 and 55 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,444,645 (Selsted *et al.*). More specifically, it is asserted that Selsted *et al.* teach a construct of (indolicidin)-[(Met)-(indolicidin)-(Met)-GST] wherein Met is a cleavage site, and GST is allegedly an anionic spacer (because GST is assertedly an acidic protein). In addition, it is further asserted that Selsted *et al.* qualifies as prior art because the Inventors' Declaration allegedly fails to provide evidence of a "cleavage site" between (peptide-spacer-peptide) constructs.

Applicants respectfully traverse this ground of rejection and submit that Selsted *et al.* fail to teach or suggest every limitation of the instant claims and, therefore, fail to anticipate the claimed invention. As described in the specification and recited in the currently pending claims, the instant invention is directed, in pertinent part, to a multi-domain fusion protein expression cassette, comprising a promoter operably linked to a nucleic acid molecule that encodes a fusion protein, wherein the encoded fusion protein comprises a structure of [(cleavage site)-(cationic peptide)-(cleavage site)-(anionic spacer peptide)]<sub>n</sub> with *n* being an integer having a value between 2 and 40, and wherein the cationic peptides have at least 30% tryptophan and have antimicrobial activity.

As an initial matter, Applicants respectfully submit that the Declaration of Burian and Bartfeld previously made of record establishes that Selsted *et al.* is not properly prior art to the instant claimed invention. In the Declaration, inventors Burian and Bartfeld declare in paragraph 7 that they had "conceived of the compositions of matter and methods as described and claimed within the subject application" (emphasis added). The description in the

specification, for example, discloses that the fusion protein expression cassettes were designed to have a cleavage site between the multiple copies of the expressed and fused cationic peptides (*see, e.g.*, specification at page 9, lines 1-4), and that the anionic spacer can have a cleavage site built into or associated with the spacer (*see, e.g.*, specification at page 13, lines 6-7; and at page 21, lines 4-9). Moreover, the figures of the fusion protein expression cassettes shown in the Declaration are essentially identical to the constructs shown in the instant application (*see, e.g.*, specification Figure 6). Therefore, contrary to the assertion in the Office Action, the cleavage site is at the very least impliedly disclosed in the Declaration, and the Office has taken an impermissible stance in doubting the objective truth of the inventors' Declaration.

Nevertheless, however, merely to expedite prosecution of the instant application and without acquiescing in this rejection as described above, Applicants have hereby amended claim 29 to recite a structure of [(cleavage site)-(cationic peptide)-(cleavage site)-(anionic spacer peptide)]<sub>n</sub> with *n* being an integer having a value between 2 and 40. Selsted *et al.* therefore fail to teach or suggest fusion protein expression cassettes according to the instant invention.

Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. § 102(e) be withdrawn because the instant claims are patentably distinct over U.S. Patent No. 6,444,645 (Selsted *et al.*).

#### **REJECTIONS UNDER 35 U.S.C. § 103(a)**

(1) In the Office Action, claims 29, 32, 35, 40, 44, 45, 47-51, 53, 55-65, and 67 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,444,645 (Selsted *et al.*) in view of U.S. Patent No. 6,180,604 (Fraser *et al.*). More specifically, it is alleged that it would have been obvious for a person having ordinary skill in the art to use an expression construct for the expression of fusion protein as taught in Selsted *et al.* to express the indolicidin sequences taught in Fraser *et al.* to achieve Applicants' invention.

Applicants respectfully traverse this ground of rejection and submit that Selsted *et al.* and Fraser *et al.*, taken alone or in combination, fail to teach or suggest the claimed invention. As noted above, Applicants respectfully submit that Selsted *et al.* is not properly prior art to the instant claimed invention in view of the inventors' Declaration previously made of record.

Nevertheless, Applicants respectfully submit that this ground of rejection has been rendered moot in view of the amendment to claim 29, as set forth above. Moreover, Selsted *et al.* describe the use of GST as a tool to isolate their hybrid protein and are silent as to the use of an anionic spacer. Hence, even assuming *arugendo* that a person having ordinary skill would even know that GST is a negatively charged protein, such a person would not be motivated to use GST as an anionic spacer in view of the Selsted *et al.* disclosure.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

(2) In the Office Action, claim 66 was rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,444,645 (Selsted *et al.*) in view of U.S. Patent No. 6,180,604 (Fraser *et al.*) and further in view of Rosenberg (*Protein Analysis and Purification: Benchtop Techniques*, Birkhauser, pp. 184-185, 1996).

Applicants respectfully traverse this ground of rejection. As set forth above, the instant rejection has been rendered moot in view of the amendment to claim 29, as set forth above. Accordingly, Applicants respectfully request that this rejection be withdrawn.

(3) In the Office Action, claim 31 was rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,444,645 (Selsted *et al.*) in view of U.S. Patent No. 6,180,604 (Fraser *et al.*) and further in view of Shen (*Proc. Natl. Acad. Sci.* 81:4627-4631, 1984), Stratagene Catalog (1993, pp. 38, 44 and 48), the Pharmacia Product catalog (1196, pp. 110 and 121-123), and Sambrook *et al.* (*Molecular Cloning: A Laboratory Manual*, Cold Spring Harbor Laboratory Press, pp. 1.14 – 1.15, 1989).

Applicants respectfully traverse this ground of rejection. As set forth above, the instant rejection has been rendered moot in view of the amendment to claim 29, as set forth above. Accordingly, Applicants respectfully request that this rejection be withdrawn.

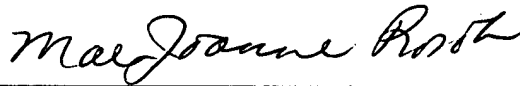
In sum, Applicants respectfully submit that the present invention satisfies the requirements of 35 U.S.C. § 103(a) and, therefore, request that these rejections be withdrawn.

Application No. 09/444,281  
Reply to Office Action dated May 14, 2004

Applicants respectfully submit that all remaining claims in the application are believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this case, the Examiner is invited to telephone the undersigned at 206-622-4900.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

A handwritten signature in cursive script, reading "Mae Joanne Rosok".

---

Mae Joanne Rosok  
Registration No. 48,903

701 Fifth Avenue, Suite 6300  
Seattle, Washington 98104-7092  
Phone: (206) 622-4900  
Fax: (206) 682-6031

505119